

**From:** [REDACTED]  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Contract for statistical analysis of breast implant data [SEC=OFFICIAL]  
**Date:** Monday, 6 May 2019 9:12:19 AM  
**Attachments:** [image001.png](#)

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Hi [REDACTED]

I am hoping to have an agenda to you later today.

As way of further background to assist in writing a plan, in 2016 the TGA undertook analysis of the available data to estimate the risk to consumers of developing breast implant associated large cell lymphoma (BIA-ALCL). The data available at that time were the number of breast implant devices supplied in Australia by each company, on an annual basis, and details of BIA-ALCL cases in Australia, with approximate implant and explant dates. Explant typically occurs with a diagnosis of BIA-ALCL as this is the part of the treatment plan. BIA-ALCL usually involves a swelling of the breast, typically 3 to 14 years after the operation to insert the breast implant. This swelling is due to an accumulation of fluid. Breast implant-associated ALCL has been known to occur as soon as 1 year after the operation and as late as 37 years after the operation. At that time the risk of ALCL was calculated at between 1-in-1,000 and 1-in-10,000.

In September 2016 the TGA has received 23 reports of BIA-ALCL since 2011. Over the past three years we have received details on further BIA-ALCL cases; the total number of cases reported to the TGA is currently 78.

Due to the increase in number of cases, and international regulators taking action in relation to particular types of breast implants, it was considered prudent to undertake analysis on the data now available to determine if there is an increased risk of developing BIA-ALCL associated with a particular type of implant, or if the overall risk of developing BIA-ALCL has altered since the initial risk assessment in 2016.

I hope this is helpful.

Kind regards

[REDACTED]

[REDACTED]

[REDACTED]

Device Vigilance and Monitoring  
Medical Devices Branch

Phone: [REDACTED]

Email: [REDACTED]

**Therapeutic Goods Administration**

Department of Health  
PO Box 100  
Woden ACT 2606 Australia

[www.tga.gov.au](http://www.tga.gov.au)



**Department of Health**

Better health and wellbeing for all Australians, now and for future generations.



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**From:** [REDACTED] [mailto:[REDACTED]]  
**Sent:** Wednesday, 1 May 2019 10:07 AM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Contract for satistical analysis of breast implant data [SEC=OFFICIAL]

Hi [REDACTED],

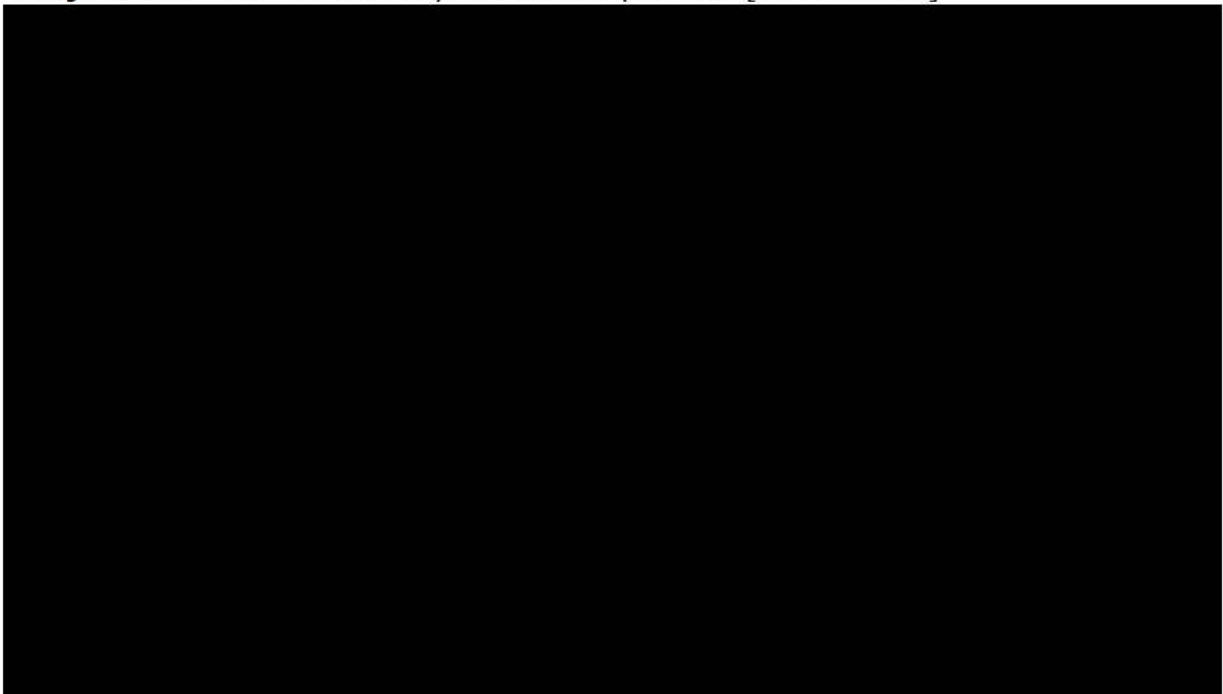
Could you please provide a short brief for the work to assist me in writing the plan? Also, it would be useful to have an agenda for Tuesday's meeting.

Kind regards,

[REDACTED]

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**From:** [REDACTED] [mailto:[REDACTED]]  
**Sent:** Tuesday, 30 April 2019 11:04 AM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** Contract for satistical analysis of breast implant data [SEC=OFFICIAL]



[REDACTED]  
[REDACTED]  
Device Vigilance and Monitoring  
Medical Devices Branch

Phone: [REDACTED]  
Alternate phone: [REDACTED] ext [REDACTED]  
Email: [REDACTED]

**Therapeutic Goods Administration**

Department of Health  
PO Box 100  
Woden ACT 2606 Australia  
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**From:** [REDACTED] [[mailto:\[REDACTED\]](mailto:[REDACTED])]  
**Sent:** Friday, 26 April 2019 11:47 AM  
**Subject:** Background information - statistical analysis meeting - 7 May 2019 [SEC=OFFICIAL]

Hi [REDACTED]

[REDACTED]

[REDACTED] We are seeking information from all sponsors/manufacturers of breast implants that have been supplied in Australia on the surface texture of their implants, as this information was not required previously, nor were the terms defined. Our Laboratories Branch will also assess samples, to confirm the classification, of all models of devices that are currently supplied in Australia. Another classification system that has been proposed (see the attached PRS publication) relates to how the surface of a breast implant is processed during manufacture; being polyurethane foam coated, salt loss, gas diffusion, imprinting, and smooth. We are requesting this information from the sponsors/manufacturers too.

[REDACTED]

[REDACTED]

Device Vigilance and Monitoring  
Medical Devices Branch

Phone: [REDACTED]  
Alternate phone: [REDACTED] ext [REDACTED]  
Email: [REDACTED]

**Therapeutic Goods Administration**

Department of Health  
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Woden ACT 2606 Australia  
[www.tga.gov.au](http://www.tga.gov.au)



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**From:** [REDACTED]  
**Sent:** Friday, 26 April 2019 10:33 AM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Request to complete COI and Deed forms - breast implants meeting - 7 May 2019  
[SEC=OFFICIAL]

Dear [REDACTED],

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Engagement & Planning Branch

Phone: [REDACTED]

Email: [REDACTED]

Therapeutic Goods Administration  
Department of Health  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)

[REDACTED]

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**From:** [REDACTED] [[mailto:\[REDACTED\]](mailto:[REDACTED])]  
**Sent:** Wednesday, 24 April 2019 4:31 PM  
**To:** [REDACTED]  
**Subject:** RE: Request to complete COI and Deed forms - breast implants meeting - 7 May 2019  
[SEC=OFFICIAL]

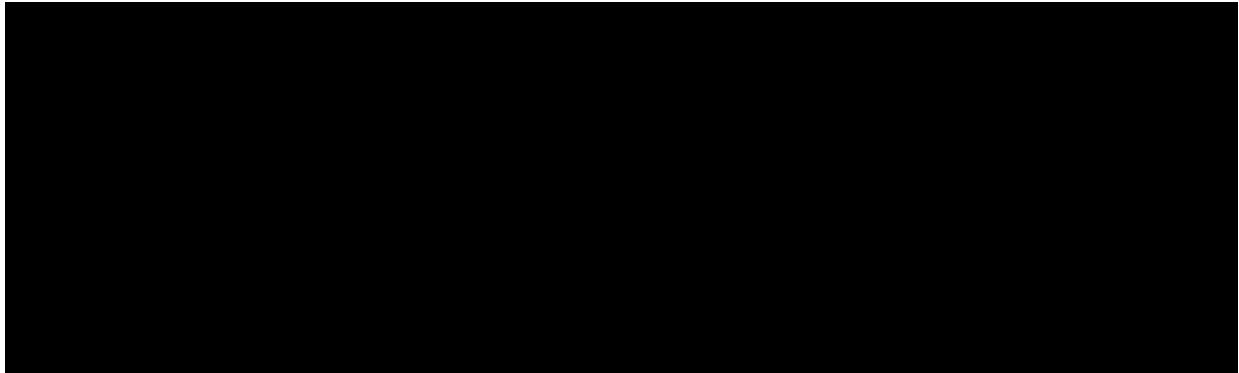
Dear [REDACTED],  
Please find attached the completed forms.  
Kind regards,  
[REDACTED]

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**From:** [REDACTED]  
**Sent:** Wednesday, 24 April 2019 9:32 AM  
**To:** [REDACTED] <[REDACTED]>; [REDACTED]  
<[REDACTED]>  
**Cc:** [REDACTED] <[REDACTED]>  
**Subject:** Request to complete COI and Deed forms - breast implants meeting - 7 May 2019  
[SEC=OFFICIAL]

Dear Dr [REDACTED],

Thank you for making the time to come to the TGA in person on 7 May 2019 to discuss the post-market review of breast implants.



[REDACTED]  
[REDACTED]  
[REDACTED]  
Regulatory Engagement & Planning Branch

Phone: [REDACTED]  
Email: [REDACTED]

Therapeutic Goods Administration  
Department of Health  
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Woden ACT 2606  
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